

returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 2 years after disposition of the outdated drugs.

(h) *Responsible persons.* Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(i) *Compliance with Federal, State, and local law.* Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

(1) Wholesale drug distributors shall permit the State licensing authority and authorized Federal, State, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, local, and DEA regulations.

(j) *Salvaging and reprocessing.* Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including parts 207, 210, and 211 of this chapter.

(Approved by the Office of Management and Budget under control number 0910–0251)

[55 FR 38023, Sept. 14, 1990, as amended at 64 FR 67763, Dec. 3, 1999]

PART 206—IMPRINTING OF SOLID ORAL DOSAGE FORM DRUG PRODUCTS FOR HUMAN USE

Sec.

206.1 Scope.

206.3 Definitions.

206.7 Exemptions.

206.10 Code imprint required.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 355, 371; 42 U.S.C. 262.

SOURCE: 58 FR 47958, Sept. 13, 1993, unless otherwise noted.

§ 206.1 Scope.

This part applies to all solid oral dosage form human drug products, including prescription drug products, over-the-counter drug products, biological drug products, and homeopathic drug products, unless otherwise exempted under § 206.7.

§ 206.3 Definitions.

The following definitions apply to this part:

The act means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).

Debossed means imprinted with a mark below the dosage form surface.

Drug product means a finished dosage form, e.g., a tablet or capsule that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

Embossed means imprinted with a mark raised above the dosage form surface.

Engraved means imprinted with a code that is cut into the dosage form surface after it has been completed.

Imprinted means marked with an identification code by means of embossing, debossing, engraving, or printing with ink.

Manufacturer means the manufacturer as described in §§ 201.1 and 600.3(t) of this chapter.

Solid oral dosage form means capsules, tablets, or similar drug products intended for oral use.

§ 206.7 Exemptions.

(a) The following classes of drug products are exempt from requirements of this part:

(1) Drug products intended for use in a clinical investigation under section 505(i) of the act, but not including drugs distributed under a treatment IND under part 312 of this chapter or distributed as part of a nonconcurrently controlled study. Placebos intended for use in a clinical investigation are exempt from the requirements of this part if they are designed to copy